In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 18-1736V
Filed: July 7, 2022
PUBLISHED

JOYCE GRUSZKA, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Master Horner Finding of Fact; Shoulder Injury Related to Vaccine Administration (SIRVA); Influenza (Flu) Vaccine; Onset

Michael G. McLaren, Black McLaren et al., PC. Memphis, TN, for petitioner.
Christine Becer, U.S. Department of Justice, Washington, DC, for respondent.

FINDING OF FACT[1]

On November 8, 2018, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012),[2] alleging that as a result of her August 18, 2017, influenza vaccination, she suffered a left Shoulder Injury Related to Vaccine Administration ("SIRVA"). (ECF No. 1.) Respondent recommended that compensation be denied, arguing, *inter alia*, that there is not preponderant evidence that petitioner's shoulder pain began within a timeframe that would support a finding of vaccine causation, namely 48 hours. (ECF No. 21.) For the reasons described below, I now issue the below finding of fact. I conclude that there is not preponderant evidence that petitioner suffered onset of new or significantly aggravated left shoulder pain within 48 hours of her August 18, 2017, flu vaccination.

[1] Because this finding of fact contains a reasoned explanation for the special master's action in this case, it will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. *See* 44 U.S.C. § 3501 (2018) (Federal Management and Promotion of Electronic Government Services). **This means the document will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information the disclosure of which would constitute an unwarranted invasion of privacy. If the special master, upon review, agrees that the identified material fits within this definition, it will be redacted from public access.

[2] All references to "§ 300aa" below refer to the relevant section of the Vaccine Act at 42 U.S.C. § 300aa-10-34 (2018).

I. Procedural History

Petitioner filed her petition on November 8, 2018. (ECF No. 1.) This case was initially assigned to the Court's Special Processing Unit ("SPU") on November 9, 2018. (ECF No. 4.) On November 12, 2018, petitioner filed an affidavit, medical records, and a statement of completion. (ECF Nos. 6, 7.) Subsequently, petitioner filed additional medical records and her second affidavit. (ECF Nos. 10, 11, 13.) On November 30, 2019, respondent filed his Rule 4 report, recommending that entitlement be denied in this case. (ECF No. 21.) Respondent raised the issue that "the record does not establish that petitioner suffered SIRVA from a vaccination within forty-eight hours and she had significant underlying chronic shoulder issues[.]" (*Id*. at 5.) Specifically, respondent noted that petitioner's treating physicians had identified advanced osteoarthritis of the affected shoulder and petitioner had reported on multiple occasions during her treatment that she had a prior history of left shoulder pain from 2015. (*Id*. at 4.) On December 10, 2019, this case was removed from the SPU and reassigned to my docket. (ECF No. 23.)

On January 8, 2020, petitioner filed a status report indicating that the parties "conferred regarding the onset issue and [could] not come to an agreement[.]" (ECF No. 24.) The parties agreed to schedule a fact-hearing for the court to hear testimony on onset and duration of symptoms. (*Id.*) However, on January 10, 2020, I instead ordered petitioner to produce any records related to her neck and/or left shoulder pain from 2015. (ECF No. 25.) Subsequently, on January 16, 2020, petitioner filed her third affidavit, a statement from her son, Joe Gruszka, and a statement from her daughter, Cynthia Kuklinski. (ECF No. 26.) On April 13, 2020, petitioner filed additional medical records from Premier Ortho and Sports. (ECF No. 29.)

On April 29, 2020, a status conference was held where I informed the parties that a fact hearing was not beneficial at this time, prior to resolving the threshold issue of petitioner's degenerative condition unrelated to vaccination. (ECF No. 30.) Petitioner was unable to produce any contemporaneous medical records corroborating her recollection that her complained-of 2015 shoulder pain was actually neck rather than shoulder pain. (*Id.*) Therefore, I ordered petitioner to file any additional records reflecting her treatment in 2015. (*Id.*) Between May and October 2020 petitioner filed additional medical and insurance records. (ECF Nos. 31, 32, 34, 36, 37, 39.) On November 13, 2020, petitioner filed a status report indicating that she had no additional records to file for respondent's and the court's review. (ECF No. 41.) On November 13, 2020, I ordered petitioner to file either a motion for a ruling on the record or an expert report to support her case. (ECF No. 42.)

On January 8, 2021, petitioner filed updated medical records from Premier physical therapy and an expert report from Dr. Srikumaran. (ECF Nos. 43, 44.) Respondent filed an expert report from Dr. Cagle Jr. on March 26, 2021. (ECF No. 47.) On May 11, 2021, a status conference was held, and the parties agreed that a fact hearing was appropriate. (ECF No. 49.) A one-day fact hearing was held on October 6, 2021. (ECF No. 51; *See* Transcript of Proceedings ("Tr") filed 11/16/2021.)

Subsequently, the parties filed a joint status report on November 5, 2021, wherein petitioner requested time to review the transcript prior to a formal fact finding. (ECF No. 54.) On November 12, 2021, the parties filed another joint status report, deferring to the court regarding any post-hearing briefing. (ECF No. 55.) I issued a NON-PDF order indicating that the parties need not file briefs in support of their respective positions, but ordered the parties to file a joint status report regarding the issue(s) presented for a finding of fact. (*See* Dkt. Text 11/12/2021.)

On November 16, 2021, the parties filed a joint status report requesting resolution of the following factual issue: "[w]hether Petitioner suffered onset of new or significantly aggravated left shoulder / arm pain within 48 hours of her August 18, 2017, flu vaccination." (ECF No. 56.) The case is now ripe for such a finding of fact.

II. Factual History

a. Medical Records

i. Pre-vaccination records

Petitioner's prior medical history is significant for bilateral knee pain, right foot / ankle pain, osteoarthritis, and ankylosing spondylitis. (Ex. 6, pp. 56-75, 91-149; Ex. 9, pp. 72-74, 76-77; Ex. 21, p. 11.) On October 21, 2015, petitioner presented to Gregory Kirwan, D.O., at Premier Orthopaedic & Sports Medicine Group ("Premier Ortho"), for a right foot assessment. (Ex. 5, p. 1.) Petitioner's past surgical history included carpal tunnel release. (*Id.*) Petitioner was assessed with right foot pain, right ankle pain, cellulitis in her right lower extremity, and rheumatoid arthritis in her foot. (*Id.* at 4-5.)

On March 27, 2017, petitioner presented to Mariclaire Schultz, D.C. for an initial exam. (Ex. 3, p. 1.) In her initial findings Dr. Schultz noted posterior right knee pain in extension, cervical instability with a prior cervical fracture, and bilateral ankle swelling. (*Id.*) There was no mention of shoulder or arm pain. (*See id.*) However, on physical examination, petitioner showed reduced range of motion in her shoulders bilaterally, and in her cervical and thoraco-lumbar regions. (*Id.* at 2.) Subsequently petitioner returned to Dr. Schultz for additional adjustments on April 3, April 10, June 5, July 18, and August 7, 2017. (*See id.* at 2-3.)

On May 22, 2017, petitioner presented to Michael S. Rosen, M.D., complaining of ongoing paresthesia in her legs, left greater than right. (Ex. 6, p. 46.) She reported a history of diabetes. (*Id.*) Dr. Rosen observed that her ankylosing spondylitis was otherwise well managed. (*Id.*) He ordered an ultrasound to rule out a Baker's cyst and ordered petitioner to return in 6 weeks. (*Id.* at 47.)

On June 7, 2017, petitioner underwent an EMG evaluation, complaining of burning pain in her calves. (Ex. 6, p. 41.) Extensive EMG evaluations were completed in the muscles of both lower extremities, innervated by lumbar nerve roots L2 through S2. (*Id.*) Daniel Kane, M.D., indicated that the electrodiagnostic testing in conjunction

with petitioner's history and physical exam revealed "electrical evidence of a very mild generalized peripheral neuropathy." (*Id.* at 41-42.) He further noted that this condition was both demyelinating and axonopathic, affecting both petitioner's motor and sensory nerves. (*Id.* at 42.) However, Dr. Kane observed that "[t]here is really not a lot of evidence to suggest a significant lumbar radiculopathy" and while there were some reinnervation potentiate noted throughout her legs, he concluded that the results were "really not too bad for patients 74 years old [*sic*]." (*Id.*) There was no evidence of lumbosacral plexopathy nor myopathy contributing to petitioner's symptoms. (*Id.*)

On July 28, 2017, petitioner presented to Nicholas Giuliani, M.D., for a follow-up visit, with no pain or stiffness, and no further paresthesia in her right leg. (Ex. 6, p. 38.) On examination Dr. Giuliani noted no synovitis, and no change in range of motion in petitioner's lumbar spine. (*Id.* at 39.) Petitioner's routine labs were normal, and she was ordered to return in four months. (*Id.* at 39-40.)

ii. Vaccination and post-vaccination records

Petitioner received an influenza vaccination in her left arm / deltoid on August 18, 2017. (Ex. 2, p. 4.) On August 22, 2017, petitioner presented to Richard Ziegler, M.D., at Premier Ortho for chronic right foot pain. (Ex. 9, pp. 28-29.) In addition to right foot pain, petitioner complained of decreased mobility, difficulty sleeping, joint tenderness, limping, night pain, swelling, and weakness. (*Id.* at 28.) Dr. Ziegler noted that petitioner was previously seen for her right foot on 10/21/15 with Dr. Kirwan. (*Id.*) Petitioner also mentioned that she saw Dr. Rosen for treatment of her arthritis. (*Id.*) There was no mention of left shoulder pain. (*Id.* at 28-29.)

On August 31, 2017, petitioner returned to Premier Ortho to Spencer Monaco, DPM, for right ankle pain. (Ex. 5, p. 14-19.) Dr. Monaco reviewed her right foot MRI and assessed petitioner with a mild ankle varus deformity. (*Id.* at 18-19.) There was no mention of shoulder pain. (*Id.* at 17-22.) Petitioner returned to Dr. Monaco again on September 28, 2017, complaining of right foot pain. (*Id.* at 20-23.) Dr. Monaco recommended an ankle brace and noted that petitioner was doing well with nonsurgical treatment. (*Id.*) Still, there was no mention of shoulder pain. (*Id.* at 23-26.)

On October 5, 2017, petitioner returned to Dr. Schultz complaining of left shoulder discomfort. (Ex. 3, p. 3.) Petitioner "[r]eported just receiving flu shot in left arm a few weeks ago (8/18/17)." (*Id.*) Dr. Schultz noted decreased range of motion to flexion, extension, hyperabduction, adduction, internal rotation, external rotation. (*Id.*) No shoulder range of motion measurements were provided. (*Id.*) Dr. Schultz performed a deep tissue massage on petitioner's left shoulder and adjusted her proximal humerus and superior / lateral scapula. (*Id.*) On November 2, 2017, petitioner returned to Dr. Schultz still experiencing pain in her shoulder. (*Id.* at 4.) Dr. Schultz repeated the same adjustments on petitioner's left shoulder. (*Id.*)

On November 28, 2017, petitioner returned to Dr. Rosen complaining of bilateral knee pain and "left shoulder pain for the past 2 months with abduction." (Ex. 6, p. 35.)

Dr. Rosen further remarked that petitioner was "doing better taking the Remicade every 4 weeks instead of every 5 weeks. She has ankylosing spondylitis along with osteoarthritis." (*Id.*) On physical examination, Dr. Rosen observed "[h]er upper and lower extremities reveal no loss of strength or motion. [Range of motion] is full." (*Id.* at 36.) Furthermore, he observed crepitation of the knees bilaterally and impingement in the left shoulder, with abduction at 160 degrees. (*Id.*) Petitioner's updated diagnoses included ankylosing spondylitis of multiple sites in the spine and primary generalized osteoarthritis. (*Id.*) Dr. Rosen ordered x-rays of the left shoulder and physical therapy, noting that if her pain continued, he planned to inject the left shoulder with steroids. (*Id.*)

On December 6, 2017, petitioner presented to Jonathan Mayer, PT, DPT, at Excel Physical Therapy. (Ex. 4, pp. 5-17.) She presented with left shoulder pain, mostly in the lateral deltoid region and worse when raising her arm overhead, reaching in overhead cabinets, reaching behind back for dressing, bathing, groom, and lifting/carrying. (*Id.* at 13.) She described her pain as a dull ache, rated at 3/10 at best and 8/10 at worst. (*Id.*) Petitioner's pain "began back in August and came on gradually." (*Id.*) Mr. Mayer further indicated that she had "a similar pain in the past about 5 years ago of [left] shoulder that responded very well with physical therapy." (*Id.*) On examination, petitioner's impingement, Empty Can, Hawkin's – Kennedy, Neers, painful arc, and infraspinatus tests were positive. (*Id.* at 14.) Mr. Mayer assessed petitioner with rotator cuff tendinitis and degenerative changes. (*Id.* at 16.) She completed ten physical therapy sessions.[3] (Ex. 4.)

On December 7, 2017, petitioner underwent x-rays of her left shoulder which revealed no fractures or dislocations, a large osteophyte overlying the inferior portion of the humeral head; degenerative changes and subchondral cysts in the region of the ureter and lesser tubercle; mild cortical irregularity overlying the lesser tubercle; no abnormal soft tissue calcifications; and mild degenerative changes in the acromioclavicular joint. (Ex. 6, p. 14.)

On December 11, 2017, petitioner presented to Dr. Schultz for a deep tissue massage and left shoulder adjustment. (Ex. 3, p. 4.) Petitioner complained of shoulder pain on passive range of motion, especially in flexion at 80 degrees and hyperabduction at 80 degrees. (*Id.*) She noted that she could not put dishes away overhead. (*Id.*) Dr. Schultz further noted "[c]urious is there a correlation between flu shot and pain / [decreased range of motion]."[4] (*Id.*)

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[3] Petitioner's final treatment session was on January 11, 2018. (Ex. 4, pp. 57-64.) In her discharge summary Mr. Mayer noted that petitioner's "shoulder was feeling much better overall. Only slight discomfort when reaching for heavier items." (*Id.* at 62.) She demonstrated "great improvements of [left] shoulder ROM, strength, stability" and was discharged home with an independent home exercise program. (*Id.* at 64.)

[4] Subsequently, petitioner returned for 18 additional deep tissue and left shoulder adjustments between February 27, 2018, and May 14, 2019. (Ex. 3, pp. 4-9; Ex. 12.) By July 23, 2018, Dr. Schultz observed that petitioner "continues with shoulder exercises, but no real progress seen." (*Id.* at 8.) No mention of petitioner's vaccination is made in the records from the remaining visits. (*See* Ex. 3, Ex. 12.)

On February 26, 2018, petitioner presented to a rheumatologist, Nicholas Giuliani, M.D. (Ex. 6, p. 10-12.) She reported that she had shoulder pain for about one year, and that PT had helped but she still had pain on abduction. (*Id.*) Petitioner described the pain as burning, and worse with movement, better with rest. (*Id.*) She also complained of right knee pain, and previous injections in both knees. (*Id.*) Dr. Giuliani remarked that her ankylosing spondylitis was otherwise doing well on Remicade. (*Id.*) On examination, petitioner had limited range of motion in the left shoulder with fluid in the joint. (*Id.*) The fluid was aspirated and showed rare white blood cells and crystals. (*Id.*) Petitioner was given a steroid injection. (*Id.*)

On June 4, 2018, petitioner returned to Dr. Rosen for a follow-up for left shoulder pain. (Ex. 6, pp. 2-4.) Petitioner had a transient response to the bursa steroid injection in her left shoulder, but the pain returned. (*Id.*) Dr. Rosen remarked that she had "known osteoarthritis of both joints" and physical therapy had not been very helpful. (*Id.*) On physical examination, petitioner could abduct the left shoulder to only 60 degrees. (*Id.*) Dr. Rosen noted that "[he] believe[d] the shoulder is significantly affected with osteoarthritis so a repair of the rotator cuff would not be practical" and referred her to Dr. Towsen for evaluation for a left total shoulder arthroplasty. (*Id.*) Dr. Rosen further observed petitioner's "ankylosing spondylitis is doing well with Remicade[.]" (*Id.*)

On June 18, 2018, petitioner presented to Adrienne Towsen, M.D., for a left shoulder evaluation. (Ex. 5, p. 24-28.) Petitioner described her symptoms as "chronic non-traumatic." (*Id.* at 24.) Dr. Towsen noted that petitioner "had an injection of the left shoulder in 2015 which gave her good relief and "she notes left shoulder pain for a few months." (*Id.*) Dr. Towsen's assessment was primary osteoarthritis of the left shoulder. (*Id.* at 28.) Her impression was that petitioner had:

> [v]ery advanced [degenerative joint disease] in her shoulder and her [range of motion] is limited. This is her non-dominant arm, but she is still very functionally limited with this arm. Her pain is constant. She did have an injection a few year[s] ago which helped her for a while. We discussed option[s] including TSA. I think she would be a great candidate for this. She has done PT in the past as well, which helped a little but I think it would only aggravate it now.

(*Id.*) Petitioner received an injection in her left shoulder and Dr. Towsen ordered her to follow-up as needed. (*Id.*)

On October 8, 2018, petitioner returned to Dr. Rosen complaining of chronic shoulder pain, reporting that she saw an orthopedic surgeon and "feels she needs a total shoulder arthroplasty." (Ex. 10, pp. 20-23.) In the plan portion Dr. Rosen noted no change to petitioner's treatment regimen. (*Id.*) Subsequently petitioner continued with anti-inflammatory drugs and Remicade for petitioner's ankylosing spondylitis through March 2019. (*Id.* at 5-15.)

On January 3, 2020, petitioner presented to Charles L. Getz, M.D., at Rothman Orthopaedics, complaining of shoulder pain of one week. (Ex. 21, p. 284.) Petitioner reported that she fell onto her left shoulder getting out of a car, resulting in a dislocation. (*Id.*) Dr. Getz observed that petitioner "has had a history of left shoulder problems for quite sometime and had an injection about five or six years ago." (*Id.*) Dr. Getz ordered and reviewed petitioner's x-rays showing a reduced shoulder joint and advanced osteoarthritis / rheumatoid arthritis of the left shoulder. (*Id.*) On physical examination, Dr. Getz observed active forward flexion elevation on the left to 30 degrees, neutral external rotation, significant crepitation through range of motion, normal internal and external rotation strength testing, normal deltoid strength in the left shoulder, and decreased active and passive range of motion in the right shoulder. (*Id.*) Dr. Getz concluded that petitioner was a candidate for shoulder replacement "based on her preexisting arthritis." (Ex. 21, p. 284-85.)

On January 22, 2020, petitioner presented to rheumatologist Michael R. Lattanzio, M.D., for a follow-up visit. (Ex. 20, p. 7.) Dr. Lattanzio noted that petitioner fell and dislocated her shoulder and was told she needs a left total shoulder arthroplasty. (*Id.*) Petitioner deferred shoulder replacement at this point. (*Id.*) On physical examination, he observed no change in her range of motion of the spine. (*Id.* at 8.) Petitioner was ordered to return in four months for a follow-up. (*Id.*)

b. Letter and Testimony from Dr. Schultz

On May 1, 2020, petitioner filed an undated letter written by Dr. Mariclaire Schultz. (Ex. 17.) Dr. Schultz indicates that her treatment of petitioner began in March 2017. (*Id.* at 1.) During that time, she was treating petitioner for "typical age-related issues." (*Id.*) Dr. Schultz notes that "[o]n October 5, 2017's visit, [petitioner] complained of an acute pain in her left shoulder with marked decrease to her shoulder [range of motion] (induced pain at the end ROM especially in forward flexion and abduction near 75 degrees; she could reach 90 degrees with my assistance." (*Id.*) From that time forward Dr. Schultz began to adjust petitioner's left AC joint, encouraged ADL modification and recommended home/aquatic exercises. (*Id.*) According to Dr. Schultz, the onset was "sudden and did not follow the typical pathway of a normal, systemic degenerative disease." (*Id.* (emphasis in original.)) Dr. Schultz "grew pretty concerned upon hearing that [petitioner] had just received the [flu] shot, especially because it was done at a pharmacy." (*Id.*)

Dr. Schultz also testified at the fact-hearing regarding her records and petitioner's treatment. (Tr. at 57-92.) Dr. Schultz testified that in her first evaluation with petitioner on March 27, 2017, petitioner did not have any significant injuries to her left shoulder. (*Id.* at 61.) She testified that petitioner had "limitation bilaterally, both sides of the shoulder, that, to me, were age-related and pretty typical. It didn't put up a red flag for me." (*Id.*) Petitioner was not in active pain at that visit, though Dr. Schultz testified that petitioner "didn't have full range of motion, but she – it was pretty balanced on both her shoulder, but no pain." (*Id.* at 62.)

Dr. Schultz testified that petitioner discussed neck pain with her in her initial visit, on March 27, 2017, "but that was a history, just to clarify, cervical instability." (Tr. at 66.) Dr. Schultz explained that petitioner would have a sore neck if she slept incorrectly, but nothing alarming. (*Id.*) In her course of treatment, Dr. Schultz testified that she spends about 40 minutes on every patient and she "deal[s] with the primary problem that [they] come in for, if [they] have one, and then [she] work[s] through, from head to toe, every single joint." (*Id*.) In every visit Dr. Schultz works through range of motion exercises on both sides, "[s]o even though I haven't written that down, that's my protocol for years and years." (*Id.* at 67.) Therefore, "if [she] had seen or felt or observed a change in [petitioner's] range of motion in her shoulders, [she] would have noted that." (*Id.*) Dr. Schultz confirmed that the lack of any notation indicates that petitioner was not complaining about shoulder problems. (*Id.*) On October 5, 2017, Dr. Schultz testified that petitioner presented with left shoulder discomfort, reporting that she had just received the flu shot in her left arm a few weeks prior. (Tr. at 68.) At that time "basically every single range of motion was impeded, and that's the first time I've ever experienced that with her." (*Id.*) Dr. Schultz did not recall having any discussions with petitioner at this visit, or her visit on November 2, 2017, about the administration of the vaccine. (*Id.* at 69-70.) In the November visit, Dr. Schultz testified "[m]aybe I thought, too, that, you know, it was age-related, that it was taking her a little bit longer to recover from it." (*Id.* at 70.) However, in the November visit she also observed that petitioner's active range of motion was between 80 and 90 degrees, which was "something she had never experienced before with me in any of her prior visits." (*Id.* at 71.) Dr. Schultz testified that this change was atypical, "when somebody would go through a typical degenerative process or an autoimmune disease, [her] experience over 24 years is that it's more of a progressive occurrence, especially with RA…[b]ut this was more this isn't getting better at all," she noted that "it's only on one side and it's extreme." (*Id.* at 74.)

In her letter Dr. Schultz noted that petitioner's diagnosis is frozen shoulder syndrome. (Tr. at 86; Ex. 17.) She testified that frozen shoulder syndrome is "when you can't get your arm into full range of motion in almost all ranges of motion, if not all." (Tr. at 86.) In contrast, she explained that "[b]ursitis and tendinitis ha[ve] more range of motion, per se, than a frozen shoulder would." (*Id.*) With a rotator cuff tear, Dr. Schultz opined that "an internal and external rotation will be the greatest deficit that you'll see." (*Id.*) However, she acknowledged that diagnosing a rotator cuff injury is difficult without an MRI. (*See id.*) Dr. Schultz never received or viewed MR images, and petitioner primarily provided verbal updates on her visits with her other doctors. (*Id.* at 87.)

On cross-examination, Dr. Schultz acknowledged that crepitus was not noted in petitioner's records until March 27, 2018. (Tr. at 89; *see* Ex. 3, p. 5.)) However, based on her recollection, Dr. Schultz testified that petitioner's crepitus began around November or December 2017. (Tr. at 89.) She also confirmed that throughout petitioner's treatment, she adjusted petitioner's neck for mechanical improvement. (*Id.* at 90.) Dr. Schultz described petitioner's onset of pain following vaccination as sudden. (Tr. at 82.) However, Dr. Schutlz could not recall petitioner's description of the onset of her shoulder pain. (Tr. at 91.) Regarding her October 2017 visit, Dr. Schultz testified that she "didn't write anything more specific as to, [] where exactly was she injected. We

didn't have a discussion on that, just that it was painful afterwards and [] that's all I can recall." (*Id.*) Dr. Schultz further testified that petitioner distinguished the pain at the top of her shoulder versus the pain in her arm: "[t]he initial pain was more of a – like a muscle pain and the – as it advanced, it became more of a deeper pain, situated around the AC joint. So that's where all of my treatments were." (Tr. at 92.) Lastly, Dr. Schultz opined that osteocytes can cause crepitus, however, it would present as a more gradual presentation. (*Id.* at 94.)

c. Petitioner's Affidavits and Testimony

Petitioner filed her first affidavit on November 12, 2018. (Ex. 1.) Prior to receiving her flu vaccination on August 18, 2017, petitioner avers that she never had any pain or loss of range of motion in her left shoulder, nor had she suffered any significant injuries or trauma to her left arm / shoulder "similar to the persistent pain [she] experienced after this vaccination." (*Id.* at 1-2.) Petitioner contends that the pain began "Immediately, within 48 hours, in [her] muscle after injection." (*Id.* at 2.) Over the next several days, petitioner described pain that "moved from [her] muscle(s) into [her] arm and shoulder with noticeable reductions of range in motion with certain activities." (*Id.*)

Petitioner filed her second affidavit on May 3, 2019. (Ex. 11.) She avers that the prior pain mentioned by her physical therapist in records from December 6, 2017, referred to "neck pain that [she] experienced in 2015." (*Id.* at 1.) Petitioner further avers that she underwent physical therapy for that pain, which helped. (*Id.*) The pain she felt in 2015 in her neck was "very different from the pain in [her] arm/shoulder now, which is in [her] upper arm area." (*Id.*) Petitioner states that she received an injection in 2015 for neck stiffness, which was "not related to shoulder pain at all." (*Id.*) She describes difficulty turning her head from side to side at the time she received the injection in 2015. (*Id.*) Petitioner also underwent physical therapy beginning in December 2017 that was not helpful. (Ex. 11, p. 2.) In the summer of 2017, petitioner avers that she presented to an orthopedic specializing in foot and ankle issues for a torn ligament. (*Id.*) Though she may have mentioned her shoulder at those visits, petitioner stresses that the primary reason for going was for the torn ligament. (*Id.*)

Petitioner filed her third affidavit on January 16, 2020. (Ex. 15.) Petitioner additionally avers that she has arthritis in several joints, and from time to time they flare up, though the pain subsides. (*Id.* at 1-2.) In contrast, her shoulder pain has never subsided, but increased. (*Id.*) Regarding the inconsistencies in her medical records, petitioner explains that when she saw her doctors, especially early on, she had not come to realize that her vaccination was the likely cause of her pain and in her visits, she gave an "approximate time frame" for the onset of her shoulder pain. (*Id.* at 2.) Looking back, she avers that "the injection site was unusually high on [her] arm." (*Id.*) Petitioner describes constant, daily, pain and struggles with activities of daily living. (*Id.* at 2-3.)

During the hearing, petitioner testified that she was in good health in August of 2017. (Tr. at 11.) She has had arthritis for approximately 20 years, and she "can go

weeks, months" without any pain, but suffers occasional flare-ups, in particular, in her right knee. (*Id.* at 12.) Petitioner also had a prior history of neck pain—"it was pain upon turning my head sideways[.]" (Tr. at 17-18.) She testified that she would often wake up with neck pain and used a special pillow to help while sleeping. (*Id.*) The references in her medical records to shoulder pain in 2015, treated with an injection, referred to injections she received "in the back along the shoulder" for her neck pain. (*Id.* (*see* Ex. 5, p. 28.)) She testified that she did not have any shoulder pain prior to the vaccination at issue. (*Id.* at 18-19.) Petitioner also receives Remicade infusions every four weeks to treat her ankylosing spondylitis. (*Id.* at 19.) Most recently, petitioner testified that she underwent back surgery on May 4th, 2021, to treat the degeneration of discs in her back and the nerves that were being impinged upon—which was causing pain in the back of her legs from her hips down to her knees. (*Id.* at 12-13.)

Regarding onset, petitioner testified that her pain and dysfunction began "within a couple of days after the vaccine." (Tr. at 14-15.) She described "[t]he soreness after the vaccination would be a tenderness…[b]ut after a couple of days that you figure you shouldn't feel that anymore if you go to use that arm, and it's a different type of pain. It's not the soreness – or tenderness would be a better word. It's painful." (*Id.* at 16.) Unlike her neck pain, petitioner testified that "[t]he shoulder pain or the arm pain that I've had since the vaccination comes from the top of my arm down to my elbow. I call it arm pain; some people might call it shoulder pain." (*Id.* at 20.) At her first visit post-vaccination, on August 22, 2017, petitioner testified that she presented to her podiatrist for foot pain after a heavy weight fell on her foot. (Tr. at 21-22 (*see* Ex. 9, pp. 28-29)) At the time she was suffering shoulder pain, although she did not discuss it with her doctor because it was not his expertise. (Tr. at 23.) On October 5, 2017, petitioner complained of left shoulder pain to her chiropractor, Dr. Shultz. (*Id.* at 23-24 (*see* Ex. 3, p. 3.)) She waited approximately five to six weeks because she "thought it would go away" and didn't realize "that it was pain from the vaccine, it was just something that I thought would go away." (Tr. at 24.) Petitioner testified, though, that she associated the pain in her shoulder with the flu shot "within a few days" or "after like 24 hours [when] it didn't feel any better, it didn't go away." (*Id.*)

Petitioner testified that she has degenerative changes in her shoulder(s) and was referred to physical therapy. (Tr. at 26.) The physical therapist performed manipulations on petitioner's arm in addition to home exercises. (*Id.*) She described the physical therapy as "[n]ot very good." (*Id.*) Petitioner's medical record from December 6, 2017, indicates that her shoulder pain "began back in August and came on gradually." (*Id.* at 27 (citing Ex. 4, p. 13.)) She testified during the hearing that she described the onset as gradual "because in the fact that the pain was there, but gradually as [she] tried to do different things, then [she] realized the limitations." (*Id.*) Regarding the note indicating that she suffered "similar pain in the past about five years ago," petitioner testified that the pain she was experiencing was in her neck. (*Id.* at 28 (*see* Ex. 4, p. 13.)) When talking about her pain with medical providers, petitioner testified that when she discussed pain from the vaccination, it was in her lower arm, from the shoulder down (gesturing to the bicep), whereas oftentimes she referred to

shoulder pain or preexisting shoulder pain in the top of her shoulder, it was through the neck (gesturing along the clavicle). (*Id.* at 28-29.)

A record from February 26, 2018, indicates that petitioner suffered left shoulder pain for about one year, or approximately February 2017. (Tr. at 32-33 (*see* Ex. 6, pp. 10-12.)) Petitioner testified that she was "not sure why it would say that. Possibly when I was giving that information, I was – my timeline was off." (Tr. at 33.) She also testified that it may have had something to do "with the fact that there was a calendar year change[.]" (*Id.*) The primary reason for that visit was for her knee(s), petitioner testified. (*Id.*) When reporting to a specialist, petitioner typically discussed "[w]hatever the body part is that [she's] there to talk about." (Tr. at 36.) She described going to a doctor for the first time, "you've got paperwork to fill out before he even sees you. That's when you can put down everything that is a health issue. But then when you go to see him….you only get to talk about the part that's actually bothering you or hurting, whatever is wrong." (Tr. at 36.)

On cross-examination, petitioner testified that the reference to "shoulder pain for the past 2 months" in Dr. Rosen's report on November 28, 2017, did not refer to the pain in her shoulder post-vaccination. (Tr. at 45-46.) That reference to shoulder pain, according to petitioner, was pain located in the "top and back part of [her] shoulder" and closer to her neck. (*Id.* at 46-47.) She explained that what "[Dr. Rosen's] referring to here is the ankylosing spondylitis is in the spine but it also progresses out to the shoulder area." (*Id.* at 47.) This pain, she testified, was also separate from the neck pain she experienced in 2015. (*Id.*) She maintained that the pain caused by her influenza vaccination was in her upper arm. (*Id.* at 47-48.) Later petitioner returned to Dr. Rosen, on June 4th, 2018, who noted that petitioner had osteoarthritis in her shoulder. (*Id.* at 48 (*see* Ex. 6, p. 3.)) Petitioner testified that she had osteoarthritis in her right shoulder, but not the left shoulder. (Tr. at 48.) She further testified that her treating doctor(s) recommended total shoulder replacement in her left shoulder, but only after she dislocated her shoulder after a fall in 2019. (Tr. at 26-27, 48-49; *but see* Ex. 6, p. 3 (recommending left total shoulder arthroplasty on 6/4/2018).)

When I asked petitioner why she discussed her prior episode of shoulder / neck pain from 2015 – in the context of her post-vaccination shoulder pain – she testified that "it's two totally different things, two totally different areas, and two totally different pains." (Tr. at 54.) Again, when I asked petitioner, why then, she discussed the 2015 injury if it was distinct, she testified that she "[didn't] recall doing that," but suggested that Dr. Rosen "would have notes in his chart – in my chart that would be sent to him from other doctors." (*Id.*) Lastly, she testified that, in her discussions with Dr. Schultz, petitioner told her "about the pain and where it was and then telling [*sic*] her about the flu shot and she then concurred that that was a possibility that that's the reason why I was still having the pain." (*Id.* at 55.)

III. Witness Statements and Testimony

a. Joesph Gruszka

On January 16, 2020, petitioner filed a statement from her son, Joe Gruszka. (Ex. 13.) Mr. Gruszka indicated that he resides with petitioner, as well as his wife and two children. (*Id.*) He recalls petitioner telling him "right after she received the shot how much it bothered her and that it was more painful then what she remembered from previous years." (*Id.*) Mr. Gruszka describes petitioner's difficulty performing daily functions, including cleaning, dressing, and cooking. (*Id.*)

Mr. Gruszka also testified during the fact hearing. (Tr. at 97-116.) He testified that petitioner had prior issues with her neck and recalled her receiving trigger point injections for her discomfort. (Tr. at 101.) Mr. Gruszka indicated that petitioner had no prior injuries or previous left shoulder problems prior to the vaccination at issue. (*Id.* at 102.) He testified that after petitioner's vaccination, he observed that the injection site was higher than normal, remarking that the Band-aid was higher up on petitioner's arm as compared to his own vaccination he received a few months later. (*Id.* at 102-03.) Mr. Gruszka observed petitioner's decreased range of motion and recalled pinning petitioner's shirt up because her shoulder was drooping. (*Id.* at 104.) He testified that petitioner's onset of shoulder pain was "pretty sudden," meaning that he "notic[ed] it within, [] a week to, you know, also that she couldn't do a lot of the chores, menial tasks." (*Id.*)

Mr. Gruszka additionally testified that he transported petitioner to some of her appointments. (Tr. at 98, 105.) He recalled that during petitioner's appointments with Dr. Rosen, for complaints involving her foot, petitioner "sa[id] something about her shoulder and the vaccine and he didn't want to discuss that. He was interested in the foot at that time." (*Id.*) Mr. Gruszka testified that, based on his daily observations, petitioner's left shoulder problems began "[l]ike the end of August of 2017." (*Id.* at 108.) Regarding his written statement, Mr. Gruszka testified that by "*right after* the shot" he meant that "in the week or two following, [he] noticed that those things were beginning to take effect." (*Id.* at 110.)

b. Cynthia Kuklinski

On January 16, 2020, petitioner also filed a statement from her daughter, Cynthia Kuklinski. (Ex. 14.) Ms. Kuklinski indicated that "[t]he pain in [petitioner's] arm started instantly, and she lost full use of her arm." (*Id.*) She states that petitioner's pain and limited use did not subside. (*Id.*) She also describes petitioner's limitations which include (1) unable to reach her left arm higher than her wrist, (2) dressing herself is uncomfortable with limited use of her arm, (3) difficulty bathing herself without full use of both arms (4) unable to use a brush and hair dryer at the same time (5) can't put on and take off a necklace and (6) unable to use a drive-thru bank or restaurant since she can't accept items with her left arm through the window. (*Id.*) According to Ms. Kuklinski, petitioner's pain and limited use of her left arm "all started with a flu vaccine." (*Id.*)

Ms. Kuklinski also testified during the fact hearing regarding petitioner's shoulder dysfunction. (Tr. 120-132.) She testified that petitioner complained of soreness in her arm the day of her influenza vaccination, August 18, 2017, or "[i]f not, it was the very next day." (*Id.* at 120.) Ms. Kuklinski recalled that petitioner "felt like [the vaccine] was administered like higher up on the arm than she had remembered in the past." (*Id.* at 121.) She testified that in the years prior to vaccination, petitioner had no left shoulder problems. (*Id.*) Ms. Kuklinski also testified that she speaks with petitioner every week, sometimes a couple times a week. (*Id.*) Petitioner's pain, she testified, did not subside with icing; and petitioner complained of pain that was unlike the initial soreness of the vaccination. (*Id.* at 123.) Despite the fact that petitioner had several doctors' appointments in the first month to two months post-vaccination where she specifically did not mention shoulder pain to her medical providers, Ms. Kuklinski testified that petitioner was in pain during that time. (*Id.* at 125-26.) She testified that petitioner likely refrained from mentioning her shoulder pain "if it was an appointment for something else, she was focusing on what that appointment was for or she thought [] it was going to go away." (*Id.* at 126.) Ms. Kuklinski did not accompany petitioner to any of petitioner's doctor's appointments in 2017. (*Id.*)

IV. Expert Reports[5]

a. Petitioner's Expert, Uma Srikumaran, M.D.[6]

Regarding petitioner's onset, Dr. Srikumaran opined that petitioner consistently and reliably reported immediate shoulder pain after vaccination to her varied medical providers, at various clinical settings. (Ex. 24, p. 10.) The first contemporaneous record to support this timing was on October 5, 2017, during petitioner's visit to her chiropractor. (*Id.* (citing Ex. 3, p. 2.)) Decreased range of motion in her shoulder was also documented in that visit. (*Id.* at 10-11.) Next, on November 28, 2017, petitioner's rheumatologist noted her shoulder abduction was 160 degrees, and described "painful impingement," which Dr. Srikumaran opines is consistent with bursitis or tendonitis, not

[5] Of note, the expert opinions filed in this case were filed prior to the fact hearing. Accordingly, these opinions do not reflect consideration of the testimonial evidence. Although the expert reports are summarized in the interest of completeness, the instant fact finding does not extend to the ultimate question of vaccine-causation.

[6] Dr. Srikumaran serves as an associate professor in the Shoulder Division at the Johns Hopkins School of Medicine and serves as the Shoulder Fellowship Director and Chair of Orthopaedic Surgery for the Howard County General Hospital. (Ex. 24, p. 1.) He also serves as the Medical Director of the Johns Hopkins Musculoskeletal Service Line in Columbia, Maryland. (*Id.*) Each year Dr. Srikumaran sees approximately 2500-3000 patients for shoulder issues and performs 400-500 shoulder surgeries annually. (*Id.*) He has treated approximately ten to twelve patients with shoulder dysfunction after vaccination in the past five years. (*Id.*) Dr. Srikumaran received his medical degree from Johns Hopkins School of Medicine in 2005. (Ex. 24, p. 1.) He completed his orthopaedic residency at Johns Hopkins Hospital and completed a shoulder surgery fellowship at Massachusetts General Hospital. (*Id.*) Dr. Srikumaran is board certified in orthopaedic surgery. (*Id.* at 10.) He has published numerous articles in the field of shoulder surgery, though none specifically related to SIRVA. (Ex. 26, p. 1.) He also peer reviews journal articles for several orthopaedic journals including The Journal of Bone & Joint Surgery, Orthopedics, Clinical Orthopedics and Related Research, and The Journal of Shoulder and Elbow Surgery. (*Id.*)

arthritis. (*Id.* at 11.) On December 6, 2017, petitioner reported that her pain began back in August 2017, starting gradually. (Ex. 4, p. 14.) Dr. Srikumaran opines that multiple examination findings from this visit are consistent with rotator cuff tendonitis or bursitis—including positive impingement signs, painful arc, and positive infraspinatus tests. (Ex. 24, p. 11.) He further opines that petitioner's radiographs demonstrate findings consistent with arthritis as well as rotator cuff pathology, specifically, the subchondral cysts of the greater and lesser tubercle. (*Id.*) Dr. Srikumaran explains that these are chronic degenerative conditions, and while vaccination did not cause these degenerative conditions, petitioner's vaccination "was the likely trigger that instigated inflammation in the bursal tissue leading to exam findings consistent with bursitis and tendonitis, and later symptoms more consistent with osteoarthritis." (*Id.*) Ultimately, he opines that "the vaccination was the trigger that initiated inflammation in [petitioner's] shoulder joint, which we would expect to have underlying age-related degeneration, causing her asymptomatic state to convert to a symptomatic one." (*Id.*)

Dr. Srikumaran opines that the vast majority of patients do not have their pain (outside of acute traumas/emergency room situations) evaluated within 48 hours. (Ex. 24, p 12.) He explains that most people are hopeful things will improve with time and basic measures and try several over the counter remedies for many weeks or months before seeking professional evaluation (particularly when they expect there is to be some pain as after any vaccination). (*Id.*) Dr. Srikumaran adds that patients have different abilities to tolerate pain and there are also costs to consider when seeking medical care. (*Id.*) In fact, he stresses that it is quite normal for someone to wait weeks or even longer prior to formal evaluation as in petitioner's case. (*Id.*)

Dr. Srikurmaran opines that whether the pain was sudden or gradual in onset is not relevant in petitioner's case because both can be consistent with a SIRVA injury. (Ex. 24, p. 12.) He opines that the onset of petitioner's symptoms is consistent with causation and is reliable based upon his experience and that of the scientific literature. (*Id.*) Dr. Srikumaran cites Arias et al., as "the best evidence as to latency of the development of symptoms" where the authors suggest a possible range from immediate to 2 months. (*Id.* (citing L.M. Arias et al., *Risk of bursitis and other injuries and dysfunctions of the shoulder following vaccinations,* 35(37) VACCINE 4870 (2017) (Ex. 26.)) Further, Dr. Srikumaran opines that "the actual amount of or type of antigenic material injected into the bursa may explain the variable symptoms patients present with as well as the variable timeframes of their presentation." (Ex. 24, p. 12.) He opines that it is plausible in some situations for a portion of the vaccination to be injected deep into the bursa while the remaining portion is injected appropriately into the muscle belly yielding variations in timing and severity of symptoms. (*Id.*) Alternatively, Dr. Srikumaran suggests that individuals are also well known to have varied immune responses based on genetics, medical co-morbidities, medications, tolerances to pain, or general well-being (stress) which can also lead to variation in timing and severity of symptoms. (*Id.*) Finally, Dr. Srikumaran opines that there were no other injuries or activities (like a fall or "unusual event") during in this time period that that may have alternatively 'triggered' the inflammation resulting in petitioner's symptoms. (*Id.*)

b. Respondent's Expert, Paul J. Cagle, M.D.[7]

Dr. Cagle opines that there is no clear link between the vaccination event and pain within 48 hours, though petitioner was seen multiple times after the vaccination without reporting the pain. (Ex. A, p. 8.) Dr. Cagle agrees with Dr. Srikumaran that there are multiple barriers patients experience to care access, and "in reality a 48 hour presentation can be difficult," however, he stresses that these points presume that the injury is acute / new. (*Id.*) In petitioner's case, Dr. Cagle opines that petitioner has "clear and undisputed preexisting shoulder pathology." (*Id.*) Therefore, a failure to report an onset of pain in relation to her flu vaccine prevents a causal link from being drawn. Without the causal 48-hour link, Dr. Cagle maintains that the pain petitioner experienced subsequently in her shoulder is easily and rationally explained by her severe shoulder arthritis. (*Id.*) Moreover, two different surgeons suggested petitioner undergo a total shoulder replacement, a treatment only recommended for long standing chronic end stage shoulder arthritis – not a recent flare up. (*Id.* (citing Michael Khazzam et al., *Management of Glenohumeral Joint Osteoarthritis,* 28 J. AM. ACAD. ORTHROP. SURG. 781(2020) (Ex. C); Salvador Israel Macias-Hernandez et al., *Glenohumeral osteoarthritis: overview, therapy, and rehabilitation,* 39(16) DISABILITY & REHAB. 1674 (2017) (Ex. D).) Dr. Cagle suggests that petitioner did not have any barriers to care where, in addition to many other office visits, petitioner was seen at Orthopaedic & Sports Medicine Associates, LTD, on August 22, 2017 (4 days post vaccination) and on August 31, 2017 (13 days post vaccination). (Ex. A, p. 8.) At these visits, Dr. Cagle points out that there is no record of shoulder pain related to a flu vaccine or any complaints of shoulder pain at all. (*Id.*) Thus, it is Dr. Cagle's opinion that the findings associated with the shoulder pain are not correlated with the vaccination and were not caused by the vaccination. (*Id.* at 10.)

V. Legal Standard Applied

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. 42 U.S.C. § 300aa-11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record

[7] Dr. Cagle serves an as assistant professor and Associate Program Director in the Department of Orthopaedic Surgery at the Icahn School of Medicine at Mount Sinai. (Ex. A, p. 1.) He is a member of the American Shoulder and Elbow Surgeons, and a faculty member of an internationally recognized shoulder surgery fellowship. (*Id.*) His current practice focuses on the shoulder, representing 95% or more of the patients and pathology he treats. (*Id.*) Dr. Cagle conducts clinical, biomechanical, and basic science research. (*Id.*) He has presented scientific work nationally and internationally; and has published over twenty articles related to shoulder injuries and surgery. (Ex. B, pp. 11-12.) Dr. Cagle is a peer reviewer for the Journal of Orthopaedic Research, Techniques in Shoulder and Elbow Surgery, and the Journal of Shoulder and Elbow Surgery. (*Id.* at 13.) He received his medical degree from Loyola University Chicago Stritch School of Medicine in 2008. (*Id.* at 2.) Dr. Cagle completed his orthopaedic residency at the University of Minnesota Academic Health center and Medical School. (*Id.*) He also completed a shoulder and elbow fellowship at Mount Sinai Hospital in New York and is board certified in orthopaedic surgery. (*Id.*)

regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." 42 U.S.C. § 300aa-13(b)(1).

The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See, e.g. Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993). Specifically, "[t]he special master or court may find the first symptom or manifestation of onset or significant aggravation of an injury, disability, illness, condition, or death described in a petition occurred within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." 42 U.S.C. § 300aa-13(b)(2).

Medical records that are created contemporaneously with the events they describe are generally considered trustworthy because they "contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993); *see also Doe v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"); *Rickett v. Sec'y of Health & Human Servs.*, 468 Fed. Appx. 952 (Fed. Cir. 2011) (non-precedential opinion). Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *19-20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005).

However, there is no presumption that medical records are complete as to all of a patient's conditions. *Kirby v. Sec'y of Health & Human Servs.*, 997 F.3d 1378, 1382-83 (Fed. Cir. 2021). Afterall, "[m]edical records are only as accurate as the person providing the information." *Parcells v. Sec'y of Health & Human Servs*., No. 03-1192V, 2006 WL 2252749, at *2 (Fed. Cl. Spec. Mstr. July 18, 2006). And, importantly, "the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance." *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991) (quoting the decision below), *aff'd per curiam,* 968 F.2d 1226 (Fed. Cir. 1992). The *Murphy* Court also observed that "[i]f a record was prepared by a disinterested person who later acknowledged that the entry was incorrect in some respect, the later correction must be taken into account." *Id.*

Although witness testimony may be offered to overcome the weight afforded to contemporaneous medical records, it must be "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). Further, the Special Master must consider the

credibility of the individual offering the testimony. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993). In determining whether to afford greater weight to contemporaneous medical records or other evidence there must be evidence that this decision was the result of a rational determination. *Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993). The special master is obligated to consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe v. Sec'y Health & Human Servs.*, 110 Fed. Cl. 184, 204 (2013) (citing § 12(d)(3); Vaccine Rule 8), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014); *see also Burns*, 3 F.3d at 417.

VI. Findings of Fact

The parties have requested a fact finding as to "[w]hether petitioner suffered new or significantly aggravated left shoulder/arm pain within 48 hours of her August 18, 2017, flu vaccination." (ECF No. 56.) For the reasons discussed below, I conclude that there is not preponderant evidence that petitioner suffered new or aggravated left shoulder pain within 48 hours of her vaccination.

After vaccination, petitioner had three orthopedic encounters where shoulder pain was not recorded before she eventually complained of left shoulder pain to her chiropractor on October 5, 2017. (Ex. 9, pp. 28-29; Ex. 5, pp. 14-23; Ex. 3, p. 3.) However, though the record of the October 5, 2017 appointment indicates that petitioner suffered shoulder discomfort subsequent to vaccination, it does not specify the timing of onset. (Ex. 3, p. 3.) Petitioner's second post-vaccination report of shoulder pain was to her rheumatologist, Dr. Rosen, on November 28, 2017. (Ex. 6, p. 35.) At that time, she reported pain "for the past 2 months with abduction." (*Id*.) Rather than placing onset at any time close to her vaccination, this would place onset at about the end of September 2017, a time falling shortly before her October 5, 2017 chiropractic appointment and potentially after the three post-vaccination orthopedic encounters at which she did not report shoulder pain.

About a week later, petitioner made a third post-vaccination report of shoulder pain at a December 6, 2017, physical therapy evaluation. (Ex. 4, p. 13.) This time she indicated that her pain "began back in August and came on gradually." (*Id*.) It was also noted, however, that the pain was "similar" to shoulder pain she had experienced in the same shoulder five years prior that responded to physical therapy, which would be around the 2012 timeframe. (*Id*.) The next day, petitioner presented for a left shoulder x-ray. (Ex. 5, p. 33.) The impression was degenerative changes of the left shoulder and the radiologist recorded a clinical history of "recurrent arthritis and pain on abduction and elevation." (*Id*.) Later, on February 26, 2018, petitioner made her fourth report of shoulder pain to a second rheumatologist, Dr. Guiliani, indicating that at that time she had been having shoulder pain "for about one year." (Ex. 6, p. 10.) This would place onset in about February of 2017, which would be about six months *pre*-vaccination.

Petitioner first sought an orthopedic evaluation of her shoulder on June 18, 2018, nearly a year after the vaccination at issue. (Ex. 5, pp. 24-28.) At that time, petitioner identified her shoulder pain as "chronic non-traumatic" and reported that she had been in pain for "a few months." (*Id*.) Petitioner again noted she had prior treatment for her left shoulder (a left shoulder injection in 2015). (*Id*. at 24.) The remainder of petitioner's medical records are less informative as to onset. However, in January of 2020, petitioner later suffered a dislocation of her shoulder after a fall and at that time reiterated to a second orthopedist that she had a history of left shoulder problems dating as far back as five or six years prior, *i.e*. about 2014 or 2015. (Ex. 21, p. 284.)

Several things are significant about the medical records spanning the year following petitioner's August 2017 flu vaccination. First, petitioner repeatedly sought orthopedic care in late August and September of 2017 without reporting her shoulder condition.[8] Second, although two of the notations of onset are *potentially* consistent with petitioner's allegation (Ex. 3, p. 3; Ex. 4, p. 13), none of the records explicitly place onset of petitioner's condition within the two days following her vaccination. Third, and relatedly, at the majority of these encounters – all but those with her chiropractor – petitioner did not even identify her vaccination as a relevant factor. In fact, petitioner instead reported to both her physical therapist and orthopedist that the pain she was experiencing was similar to pain she had previously experienced years prior. (Ex. 4, p. 13; Ex. 5, p. 27.) She also reported to the orthopedist that her shoulder pain was "chronic non-traumatic" and the physical therapist recorded that the mechanism of injury was "overuse." (*Id*.) Her radiologist recorded that her pain was due to a history of recurrent arthritis. (Ex. 5, p. 33.) And, fourth and finally, several of petitioner's medical records identify periods of onset that are incompatible with petitioner's allegations. (Ex. 6, p. 35 (placing onset about a month post-vaccination); Ex. 6, p. 10 (placing onset about 6 months pre-vaccination); Ex. 5, p. 24 (placing onset "a few months" prior to June of 2018). Thus, considered as a whole, the medical records do not support onset of shoulder pain within 48 hours of vaccination.

An additional consideration arises in that petitioner's chiropractor, Dr. Schultz, also testified.[9] Dr. Schultz is the sole treater to whom petitioner reported her shoulder

[8] Given that petitioner was presenting for other complaints relating to her foot and ankle, this is not dispositive. There is no presumption that petitioner's orthopedic encounter records are complete as to conditions unrelated to the problem for which she was seeking treatment. *Kirby v. Sec'y of Health & Human Servs.,* 997 F.3d 1378, 1382-83 (Fed. Cir. 2021). However, as explained further below, petitioner is also unpersuasive in seeking to explain why she did not initially report her shoulder pain to her treaters at Premier Orthopedics.

[9] While treating physician opinions expressed in written records are considered very often in this program, treating physician testimony is comparatively rare. Although special masters are obligated to consider only medical opinion that has a reliable basis, cross-examination of treating physicians is generally not considered necessary because their own medical records are in themselves generally considered facially trustworthy. *Andreu v. Sec'y of Health & Human Servs*., 569 F.3d 1367, 1383 (Fed. Cir. 2009) (citing *Cucuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).) However, when a treating physician offers a statement that is not contemporaneous to events and is not within the context of diagnosis and treatment, a special master does not err in concluding that it is not entitled to the same deference as contemporaneous medical records, even records created by the same physician. *See Milik*

pain as a post-vaccination phenomenon. (Ex. 3, p. 3.) Additionally, Dr. Schultz specifically questioned in her notes whether there was any correlation between petitioner's flu vaccine and her shoulder injury. (Ex. 3, p. 4 (noting "[c]urious is there a correlation between flu shot and pain/dec r.o.m.").) Ultimately, however, Dr. Schultz's testimony did not bolster petitioner's allegations with regard to onset. Dr. Schultz testified at length regarding the fact that petitioner's presentation was different pre- and post-vaccination; however, petitioner's first post-vaccination appointment with Dr. Schultz was two months after her prior August 7, 2017 encounter and more than a month and a half post-vaccination, meaning she was not in a position to personally observe the onset of petitioner's shoulder pain as it developed. (Ex. 3, p. 3.) With regard to onset of left shoulder pain, Dr. Schultz indicated that petitioner had experienced a "sudden" onset; however, she ultimately testified as follows:

> Q. When you were answering Mr. Webb's questions, he asked you about your characterization of Petitioner's – the onset of Petitioner's pain as being sudden.
> A. Yes.
> Q. And I understood your answer to be focusing primarily on your observations comparing your initial evaluation of her range of motion and the range of motion when she first presented to you with this problem. Can you recall anything about how Petitioner described the onset of this shoulder pain when she first saw you?
> A. Honestly, no. I don't remember specifics since it's been a while. The only thing that – again, you're referring to December, right, when we talked about things in December?
> Q. I was thinking of October when she first came to you after the vaccination.
> A. She – yeah, I didn't – I didn't write anything more specific as to, you know, where exactly was she injected. We didn't have a discussion on that, just that it was painful afterwards and – yeah, that's all I can recall.

(Tr. at 90-91.)

Thus, Dr. Schultz could not meaningfully add to her contemporaneous records in terms of identifying the onset of petitioner's condition. And, as discussed above, when considering the contemporaneous medical records as a whole, including Dr. Schultz's records, there is not preponderant evidence of onset occurring within 48 hours of vaccination. Dr. Schultz's characterization of petitioner's shoulder pain as "sudden" is

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v. Sec'y of Health & Human Servs., 822 F.3d 1367, 1381-82 (Fed. Cir. 2016). For example, in *Milik*, a treating physician recorded in his initial treatment record that a child's developmental delay had been "longstanding" in contrast to an "acute" onset of limping. *Id.* In a much later letter written to the court, the doctor sought to recharacterize the word "longstanding" as meaning in effect only preexisting, which the special master thought incompatible with the original record that contrasted "longstanding" against "acute." *Id.* The Federal Circuit held that it was not error for the special master to credit the plain meaning of the original treatment record over the physician's subsequent reinterpretation of the notation. *Id*. Accordingly, Dr. Schultz's testimony is subject to the same credibility determination as any other witness, as explained in the preceding section.

not supported by her own contemporaneous records and is directly contradicted by other of petitioner's contemporaneous medical records. (*See* Ex. 4, p. 13 (petitioner reporting "[p]ain began back in August and came on gradually").) And again, pertinent to this point, Dr. Schultz did not actually see petitioner until October 5, 2017 – two months since she had last seen her and more than a month and a half post-vaccination. Moreover, petitioner confirmed in her own hearing testimony that she did perceive the onset of her shoulder condition to be gradual and confirmed that she had reported a gradual onset to her physical therapist. (Tr. 27.)

Contrary to the above, petitioner testified in accordance with her allegations that she did experience shoulder pain within 48 hours of vaccination. (Tr. at 14-15.) In that regard, petitioner attempted to explain away the medical records incompatible with her claim. (*Id.* at 26-36, 45-50.) However, this testimony was not persuasive enough to overcome the evidentiary weight of the contemporaneous medical records.

Petitioner testified that she did not initially report her shoulder pain on August 22, 2017, because she was seeing a podiatrist at that time, suggesting her shoulder complaint was outside his expertise. (Tr. at 21-22.) Petitioner suggested that when seeing a specialist she typically limited her discussion to the specific body part prompting the appointment. (*Id.* at 33.) However, though she was seeking care for her foot and ankle, petitioner was at that time seeking treatment at an orthopedic and sports medicine practice. (*See* Exs. 5, 9, *passim*.) Moreover, she did ultimately seek treatment for her shoulder condition from that same practice group and, contrary to her stated rationale, did raise her shoulder complaint with her rheumatologist despite being there to be seen with regard to knee pain. (Ex. 5, p. 24; Ex. 6, p. 35.) Additionally, petitioner confirmed her ability to get an appointment with this orthopedic practice group within one to two weeks. (Tr. at 22.) Accordingly, even if petitioner did refrain from raising her shoulder pain because her specific appointment was in relation to her foot, she does not appear to have been prevented from seeking a separate appointment for her shoulder during this period.

Petitioner also indicated in her affidavit that the inconsistencies in her earlier records are explained by the fact that she had not yet come to realize that her vaccination was the likely cause of her pain. (Ex. 15, p. 2.) She averred that

> I realize there is some perceived inconsistencies regarding the start of my pain following the vaccine based on people's review of my medical records. When I was seeing my doctors, especially early on, I had not come to realize that the vaccination was the likely cause of my pain. I certainly was not focused on the exact date when everything started, I gave an approximate time frame with the goal of receiving relief.

(Ex. 15, p. 2.) During the hearing, however, petitioner testified:

> Q. Did you associate the pain in your shoulder with the flu shot from the very beginning?

A. Within a few days, I did.
Q. At what point did you determine that this was not the normal pain after a vaccination that you've experienced in years past?
A. When after like 24 hours it didn't feel any better, it didn't go away.

(Tr. at 24-25.)

Thus, during the hearing petitioner directly contradicted her previously stated rationale for having provided differing periods of onset to her treating physicians. Moreover, petitioner's medical records reflect that these inconsistencies occurred *after* she had raised a suspicion of post-vaccination shoulder pain to Dr. Schultz. That is, after noting the fact of her prior vaccination when reporting her symptoms to Dr. Schultz on October 5, 2017, petitioner subsequently reported differing periods of onset to three different doctors and a physical therapist without ever again having her vaccination recorded as potentially relevant. (Ex. 4, p. 13; Ex. 5, p. 24; Ex. 6, pp. 10, 35.) Moreover, even apart from timing, petitioner offered histories including factors pointing away from her vaccine as causally relevant. (See Ex. 4, p. 13 (reporting gradual onset due to chronic symptoms, noting prior similar shoulder pain five years prior, and identifying overuse as mechanism of injury); Ex. 5, p. 24 (reporting symptoms as "chronic non-traumatic" and reporting relief from a prior left shoulder injection). Thus, even if crediting that portion of petitioner's testimony expressing an initial hesitation in attributing her pain to her vaccination, that testimony still does not explain the histories contained in her medical records.

Petitioner also sought in her testimony to distinguish her reports of post-vaccination shoulder pain from other reports of shoulder pain in her records that she contends referred instead to neck pain. (Tr at 28-30.) In her affidavit, petitioner indicated that her 2015 complaint was "neck stiffness," suggesting that "[i[t was not related to shoulder pain at all. I had difficulty turning my head from side to side . . ." (Ex. 11, p. 2.) During the hearing, however, petitioner's description of what constituted her prior neck pain was somewhat ambiguous as petitioner confirmed that by "neck" she really meant the top of her shoulder in the area of the clavicle. (Tr. 29.) Moreover, petitioner does acknowledge experiencing flares of arthritis in her shoulder. (Tr. at 20-21.)

In any event, regardless of how petitioner subjectively characterized her pain anatomically in testimony, petitioner is unpersuasive in suggesting that her records from the post-vaccination period can be parsed in this manner. Notable to this point, petitioner reported her prior history of shoulder pain only to her orthopedists and physical therapist (who were treating her shoulder specifically) rather than to either her chiropractor or rheumatologists (who were treating cervical instability and ankylosing spondylitis). (*Compare* Ex. 4 (Mr. Mayer (physical therapist)), Ex. 5 (Dr. Towsen), Ex. 21 (Dr. Getz) *and,* Ex. 3 (Dr. Schultz); Ex. 6 (Drs. Rosen and Giuliani).) Additionally, her physical therapist explicitly indicated that the current episode of what was described as shoulder pain was "similar" to the prior episode. (Ex. 4, p. 13) Petitioner's records also confirm that she had osteoarthritis and reduced range of motion inclusive of her left

shoulder prior to vaccination (Ex. 3, p. 2; Ex. 5, p. 30[10]) and her own testimony explained that she experienced occasional flares of her arthritis in her shoulder (Tr. at 20-21). Further to these points, as discussed above, petitioner did not confidently or consistently identify a clear timing of onset. Instead, petitioner described onset as gradual and reported her condition as chronic. Furthermore, she mostly did not discuss the fact of her vaccination when seeking care and she referenced her prior history of left shoulder pain repeatedly.[11]

Nonetheless, petitioner testified as follows:

> Q. Okay. Do you think discussing your prior episode of shoulder/neck pain from 2015 is helpful in determining what is happening with your shoulder post-vaccination?
> A. It is helpful – it's two totally different things, two totally different areas, and two totally different pains.
> Q: Right. If they are distinct, why bring them up when you're giving the history to the doctor is my question?
> A. I don't recall doing that. In other words, if its – if it's Dr. Rosen, he would have notes in his chart – in my chart that would be sent to him from other doctors. It would be the same with my primary.

(Tr. at 54.)

However, the notations at issue are included in sections of the medical record dealing with either subjective complaints or the history of present illness and are interspersed with statements directly attributed to petitioner herself and/or confirming she discussed her preexisting osteoarthritis with her physicians at the time, strongly suggesting these notations originated from petitioner's own provided history rather than being copied over from prior notes. (Ex. 4, p. 13 (noting that "*[p]atient denies* any clicking/popping. Patient has had a similar pain in the past about 5 years ago of the L shoulder that responded very well with physical therapy. *Patient denies* any numbness/tingling in LUE . . ." (emphasis added)); Ex. 5, p. 24 ("She had an injection of the left shoulder in 2015 which gave her good relief. *She notes* left shoulder pain for a few months" (emphasis added)); Ex. 21, p. 284 (noting in "HPI" that "[s]he has a history of left shoulder problems for quite sometime [*sic.*] and had an injection about five or six

[10] Although the x-ray confirming degenerative changes within petitioner's left shoulder post-dates petitioner's vaccination, both parties' experts agree that petitioner had preexisting osteoarthritis, though petitioner's expert opined it was asymptomatic. (Ex. A, p. 6; Ex. 24, p. 10.) Respondent's expert more specifically explains that this is confirmed by the December 7, 2017 x-ray. (Ex. A, p. 6.) Notably, the clinical history associated with the x-ray is that petitioner presented "with a history of recurrent arthritis and pain on abduction and evaluation. No trauma." (Ex. 5, p. 30.)

[11] To be clear, there is evidence of record suggesting petitioner also had a history of neck pain. (Ex. 3, pp. 1-11.) However, the issue presented in this case is that petitioner is explicitly and specifically recorded by her treating physicians as reporting prior *shoulder* pain at key medical encounters. Petitioner is unpersuasive in suggesting her medical records should be reinterpreted so that the specific references to shoulder pain are understood as neck pain, but this does not mean petitioner never had any neck pain.

years ago" and in "Notes" stating that "I discussed with the patient that she is a candidate for shoulder replacement based on her preexisting arthritis").) Further, these reports of prior shoulder pain were made to three separate treaters at three separate facilities. (Ex. 4, p. 13 (Mr. Mayer of Excel Physical Therapy), Ex. 5, p. 24 (Dr. Towsen of Premier Orthopedics and Sports Medicine), and Ex. 21, p. 284 (Dr. Getz of Rothman Orthopedics).) Additionally, petitioner's medical records reflect that she continued to report a prior history of left shoulder pain dating back to 2015 even after filing her affidavit in this case purporting to clarify that her prior history was of neck pain rather than shoulder pain. (*Compare* Ex. 11 (affidavit dated May 2, 2019) and Ex. 21, p. 284 (orthopedic encounter dated January 3, 2020).) Petitioner told Dr. Getz in January of 2020 that she had prior left shoulder problems dating back five or six years. (Ex. 21, p. 284.) This appointment was unequivocally in treatment of her shoulder as it was in follow up to a previously reduced dislocation. Thus, it is clear that petitioner is explaining her condition to the court in a manner inconsistent with how she is continuing to discuss her condition with her treating orthopedist. For all these reasons, petitioner is unpersuasive in asserting that her reports of prior left shoulder pain are in any way misstated or otherwise appear in her records by error.

Petitioner also provided testimony from her children. Ms. Kuklinksi, who speaks to petitioner once or twice a week, testified that petitioner complained of post-vaccination pain either the day of the vaccination or the next day. (Tr. at 120-21.) Ms. Kuklinksi, who did not accompany petitioner to any of her medical appointments in 2017, further testified that petitioner likely would not have reported her shoulder pain if her appointment was for something else. (*Id.* at 126.) However, Joseph Gruszka, who lives with petitioner and accompanied her to at least some medical appointments, testified that petitioner did raise her shoulder pain at an appointment initially made for a different condition. (*Id.* at 105.) He also testified that while petitioner had seemingly normal post-vaccination discomfort, he first noticed petitioner having difficulty with her shoulder within a week. (*Id.* at 104.) Petitioner herself also testified that she experienced typical post-vaccination tenderness that was separate from the painfulness she described as arising "after a couple of days." (*Id.* at 16.) This testimony does not have the consistency necessary to outweigh the competing medical record evidence.

Finally, an additional question is whether the expertise reflected in petitioner's expert medical opinion helps to inform the factual question at issue. Petitioner's expert, Dr. Srikumaran, opines that petitioner's preexisting osteoarthritis is unlikely to explain her post-vaccination symptoms. (Ex. 24, *passim*.) However, his assessment is based on a mistaken assumption that "Ms. Gruska (*sic*.) consistently and reliably reports immediate shoulder pain after vaccination to her varied medical providers, at various clinical settings including office and treatment visits over a long period of time . . ." (*Id*. at 10.) With regard to the above-discussed reports of prior shoulder injections from 2015, Dr. Srikumaran does provide evidence that petitioner's October 6, 2014, Sodium hyaluronate injection (Ex. 18, p. 49) is not approved for use in the shoulder; however, he indicates that petitioner's October 10, 2014, methylprednisolone injection (Ex. 18, p. 53) is routinely injected in all joints of the body. (Ex. 24, p. 10.)

VII. Conclusion

In light of all of the above and considering the record as a whole, the evidence preponderates in favor of a finding that petitioner experienced prior episodes of left shoulder pain and also experienced a *gradual* onset of similar left shoulder pain with an indeterminate initial onset occurring sometime between late August and early October of 2017. However, there is not preponderant evidence that onset of left shoulder pain, whether new or aggravated, occurred within 48 hours of her August 18, 2017, vaccination.

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master